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college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose.

(b) Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional.

(c) Is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed. In a State that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a “registered dietitian” by the Commission on Dietetic Registration or its successor organization, or meets the requirements of paragraphs (a) and (b) of this section.

(d) *Exceptions.* (i) A dietitian or nutritionist licensed or certified in a State as of December 21, 2000 is not required to meet the requirements of (a) and (b) of this section.

(ii) A “registered dietitian” in good standing, as recognized by the Commission of Dietetic Registration or its successor organization, is deemed to have met the requirements of (a) and (b) of this section.

[66 FR 55331, Nov. 1, 2001; 67 FR 20684, Apr. 26, 2002]

Subpart H—Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements

SOURCE: 65 FR 83148, Dec. 29, 2000, unless otherwise noted.

§ 410.140 Definitions.

For purposes of this subpart, the following definitions apply:

ADA stands for the American Diabetes Association.

Approved entity means an individual, physician, or entity accredited by an approved organization as meeting one of the sets of quality standards described in § 410.144 and approved by CMS under § 410.141(e) to furnish training.

Deemed entity means an individual, physician, or entity accredited by an approved organization, but that has not yet been approved by CMS under § 410.145(b) to furnish training.

Diabetes means diabetes mellitus, a condition of abnormal glucose metabolism diagnosed using the following criteria: A fasting blood sugar greater than or equal to 126 mg/dL on two different occasions; a 2 hour post-glucose challenge greater than or equal to 200 mg/dL on 2 different occasions; or a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.

NSDSMEP stands for the National Standards for Diabetes Self Management Education Programs.

Organization means a national accreditation organization.

Rural means an area that meets one of the following conditions:

(1) Is not urbanized (as defined by the Bureau of the Census) and that is designated by the chief executive officer of the State, and certified by the Secretary, as an area with a shortage of personal health services.

(2) Is designated by the Secretary either as an area with a shortage of personal health services or as a health professional shortage area.

(3) Is designated by the Indian Health Service as a health service delivery area as defined in § 36.15 of this title.

Training means outpatient diabetes self-management training.

[65 FR 83148, Dec. 29, 2000, as amended at 68 FR 63261, Nov. 7, 2003; 76 FR 73471, Nov. 28, 2011]

§ 410.141 Outpatient diabetes self-management training.

(a) *General rule.* Medicare Part B covers training defined in § 410.140 if all of the conditions and requirements of this subpart are met.

(b) *Conditions for coverage.* The training must meet the following conditions:

(1) *Training orders.* Following an evaluation of the beneficiary's need for the training, the training is ordered by the physician (or qualified nonphysician practitioner) (as defined in § 410.32(a)(2)) treating the beneficiary's diabetes.

(2) *Plan of care.* It is included in a comprehensive plan of care established by the physician (or qualified nonphysician practitioner) treating the beneficiary for diabetes that meets the following requirements:

(i) Describes the content, number of sessions, frequency, and duration of the training as written by the physician (or qualified nonphysician practitioner) treating the beneficiary.

(ii) Contains a statement specified by CMS and signed by the physician (or qualified nonphysician practitioner) managing the beneficiary's diabetic condition. By signing this statement, the physician (or qualified nonphysician practitioner) certifies that he or she is managing the beneficiary's diabetic condition and the training described in the plan of care is needed to ensure therapy compliance or to provide the beneficiary with the skills and knowledge to help manage the beneficiary's diabetes. The physician's (or qualified nonphysician practitioner's) statement must identify the beneficiary's specific medical conditions (described in paragraph (d) of this section) that the training will address.

(iii) Provides that any changes to the plan of care are signed by the physician (or qualified nonphysician practitioner) treating the beneficiary.

(iv) Is incorporated into the approved entity's medical record for the beneficiary and is made available, upon request, to CMS.

(3) *Reasonable and necessary.* It is reasonable and necessary for treating or monitoring the condition of a beneficiary who meets the conditions described in paragraph (d) of this section.

(c) Types and frequency of training—
(1) Initial training—

General rule. (i) Medicare Part B covers initial training that meets the following conditions:

(A) Is furnished to a beneficiary who has not previously received initial training under this benefit.

(B) Is furnished within a continuous 12-month period.

(C) Does not exceed a total of 10 hours.

(D) Except as permitted under paragraph (c)(1)(ii) of this section, 9 hours of the training are furnished in a group setting consisting of 2 to 20 individuals

who need not all be Medicare beneficiaries.

(E) Is furnished in increments of no less than one-half hour.

(F) May include 1 hour of individual training for an assessment of the beneficiary's training needs.

(ii) *Exception.* Medicare covers training on an individual basis for a Medicare beneficiary who meets any of the following conditions:

(A) No group session is available within 2 months of the date the training is ordered.

(B) The beneficiary's physician (or qualified nonphysician practitioner) documents in the beneficiary's medical record that the beneficiary has special needs resulting from conditions, such as severe vision, hearing, or language limitations that will hinder effective participation in a group training session.

(2) *Follow-up training.* After receiving the initial training described in paragraph (c)(1) of this section, Medicare covers follow-up training that meets the following conditions:

(i) Consists of no more than 2 hours individual or group training for a beneficiary each year.

(ii) Group training consists of 2 to 20 individuals who need not all be Medicare beneficiaries.

(iii) Is furnished any time in a calendar year following the year in which the beneficiary completes the initial training.

(iv) Is furnished in increments of no less than one-half hour.

(v) The physician (or qualified nonphysician practitioner) treating the beneficiary must document, in the referral for training and the beneficiary's medical record, the specific medical condition (described in paragraph (d) of this section) that the follow-up training must address.

(d) *Beneficiaries who may be covered.* Medicare Part B covers outpatient diabetes self-management training for a beneficiary who has been diagnosed with diabetes.

(e) *Who may furnish services.* Training may be furnished by a physician, individual, or entity that meets the following conditions:

(1) Furnishes other services for which direct Medicare payment may be made.

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(2) May properly receive Medicare payment under § 424.73 or § 424.80 of this chapter, which set forth prohibitions on assignment and reassignment of benefits.

(3) Submits necessary documentation to, and is accredited by, an accreditation organization approved by CMS under § 410.142 to meet one of the sets of quality standards described in § 410.144.

(4) Provides documentation to CMS, as requested, including diabetes outcome measurements set forth at § 410.146.

[65 FR 83148, Dec. 29, 2000, as amended at 68 FR 63261, Nov. 7, 2003; 76 FR 73471, Nov. 28, 2011]

§ 410.142 CMS process for approving national accreditation organizations.

(a) *General rule.* CMS may approve and recognize a nonprofit or not-for-profit organization with demonstrated experience in representing the interest of individuals with diabetes to accredit entities to furnish training.

(b) *Required information and materials.* An organization requesting CMS's approval and recognition of its accreditation program must furnish to CMS the following information and materials:

(1) The requirements and quality standards that the organization uses to accredit entities to furnish training.

(2) If an organization does not use the CMS quality standards or the NSDSMEP quality standards described in § 410.144(a) or (b), a detailed comparison including a crosswalk between the organization's standards and the CMS quality standards described in § 410.144(a).

(3) Detailed information about the organization's accreditation process, including all of the following information:

(i) Frequency of accreditation.

(ii) Copies of accreditation forms, guidelines, and instructions to evaluators.

(iii) Descriptions of the following:

(A) The accreditation review process and the accreditation status decision making process.

(B) The procedures used to notify a deemed entity of deficiencies in its outpatient diabetes self-management

training program and procedures to monitor the correction of those deficiencies.

(C) The procedures used to enforce compliance with the accreditation requirements and standards.

(4) Detailed information about the individuals who perform evaluations for the organization, including all of the following information:

(i) The education and experience requirements for the individuals who perform evaluations.

(ii) The content and frequency of continuing education furnished to the individuals who perform evaluations.

(iii) The process used to monitor the performance of individuals who perform evaluations.

(iv) The organization's policies and practices for participation in the accreditation process by an individual who is professionally or financially affiliated with the entity being evaluated.

(5) A description of the organization's data management and analysis system for its accreditation activities and decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) A description of the organization's procedures for responding to and investigating complaints against an approved entity, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsmen programs, and CMS.

(7) A description of the organization's policies and procedures for withholding or removing a certificate of accreditation for failure to meet the organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

(8) A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that will serve as a basis for accreditation if CMS approves the organization.

(9) A list of all of the approved entities currently accredited to furnish